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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,748

09/09/2003

Paul J. Thompson

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BOSTON, MA 02109

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/658,748

Applicant(s)

THOMPSON, PAUL J.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 10-21, 24-29 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-5, 10-13, and 15 of U. S. Patent No. 6,623,491. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the application are merely broader than the patent claims.

3. Claims 10-13, 16-18, 20-22, 24-25, 27 and 29 of the instant application conflict with claims 1-8, 10-11, 13-14, and 19 amended on 10/19/06 of Application No.

09/954,763. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either

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cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. Applicant states in the Remarks dated 09/17/05 that the claims of instant application do not recite an identical or analogous limitation to the claims in the conflicting application. Examiner asserts that the "treatment site" found in Claim 10 of the instant application is analogous to the "stent mounting location" found in claim 1 of the conflicting application. Therefore the rejection is upheld.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

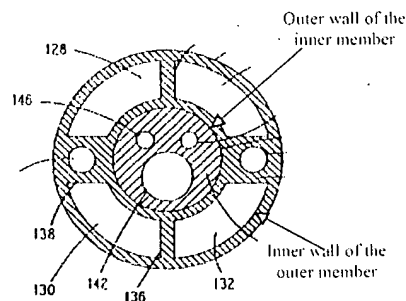
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 10-15, 17, 19-24, 27, 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mische et al. (USPN 5,279,546):**

6. As to claims 10, 20, 21, and 27, Mische discloses a treatment system (Figures, 1-3), comprising: an elongated outer member (70) having a distal end and a proximal end, the outer member having an inner wall that defines a first lumen (120); an elongated inner member (72) having a distal end and a proximal end, the inner member having an inner wall that defines a second lumen (142, 144, 146), the inner member being received within the first lumen of the outer member, the outer member (70) and the inner member (72) axially slidable relative to one another (Col 4, line 40-41); the

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outer member being sized to pass through a body lumen with the distal end being advanced toward a treatment site and with the proximal end being external to the body lumen for manipulation by an operator; the inner member having an outer wall that defines a treatment region at the distal end of the inner member (86); *a fluid passage is defined by the outer wall of the inner member and the inner wall of the outer member* (126, 128, 130, 132) [The outer wall of the inner member and the inner wall of the outer member do "define" or "show a boundary or outline" of the fluid passage. In other words the two members define the limits of the fluid passage and the fluid passage falls within the boundaries defined by the two members. That does not necessarily mean that the fluid lumen completely extends to the outermost limits of the boundary defined by the two members. Nor does it exclude other elements from falling within the boundary defined by the two members (see below).]; a plurality of circumferentially spaced-apart structures (134, 136, 138, 140) disposed along a majority of the length of the fluid passage *between* the outer wall of the inner member and the inner wall of the outer member with the circumferentially space-apart structures spacing the outer wall of the inner member from the inner wall of the outer member; and a port in communication with the fluid passage (46) (Col 4, line 9-10).



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7. As to claim 11 and 27, the spaced apart structures extend an entire length from the proximal end of the outer member to the treatment region (the treatment region being defined by balloons (74) and (86)). As to claim 12 and 22, the spaced apart structures are disposed to maintain the inner member centrally positioned within the outer member and prevent the inner member from moving radially (Col 5, lines 32-36). As to claim 13, the spaced apart structures are carried on the wall of the inner member and extend radially outward towards the outer member. When the device, as a whole is delivered to the treatment site, the outer and inner catheter will travel together and so the spaced apart structures will be carried on the inner member. As to claim 14, the guidewire is element (11). As to claim 15, the spaced apart structures are shaped to define voids that extend the length of the fluid passage. As to claim 17 and 24, the base portion of the spaced apart structures is connected to the wall or the lumen-defining portion of the inner member and the opposite end engages the wall of the outer member. Although the inner catheter is not fixedly connected to the outer catheter, it is, nonetheless, connected. Since the catheters are assembled together as one structure, they are thus considered connected. As to claims 19 and 26, since the opposite ends of the spaced apart structure abut the inner surface of the outer member, which is circumferential, the opposite ends are slightly rounded.

8. As to claim 23, the spaced apart structures prevent the inner member from contacting the outer member.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 10-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krivoruchko et al. (USPN 6,786,918) in view of Fitz (USPN 6,129,700).

11. Krivoruchko discloses a catheter device comprising an elongated outer member (26) having an inner wall that defines a first lumen (30), an elongated inner member (24) having an inner wall that defines a second lumen and being received within the first lumen of the outer member (see figure 2). The outer member and the inner member are axially slidable relative to one another (Col 4, line 40). The outer member is sized to be passed through a body lumen, and the inner member has an outer wall that defines a treatment region (28). A fluid passage is defined by the outer wall of the inner member and the inner wall of the outer member and a port is in communication with the fluid passage (Col 6, lines 12-20). A plurality of circumferentially spaced-apart structures (62) extends between the outer wall of the inner member and the inner wall of the outer member. The circumferentially spaced-apart structures have an uninterrupted length and are coextensive and with a majority of the lengths of the inner and outer members (Col 4, line 25-26). The spaced-apart structures include a base portion connected to the inner member, and an opposite end that engages the inner surface of the outer member (see Figure 5). The base portions of the spaced apart structures are integral with the

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lumen-defining portion of the inner member, and the opposite ends are rounded (see Figure 5). the spaced apart structures maintain that the inner member is centrally positioned within the outer member (Col 4, line 37). The spaced apart structures are carried on the wall of the inner member, extend radially outward, and define voids (68A-F).

12. Krivoruchko fails to include a discharge opening in fluid communication with the fluid passage and extending through a wall of the outer shaft to permit fluid flow from the port to the body lumen.

13. Fitz discloses another stent delivery catheter and teaches that a discharge opening (54) located through the wall of the outer shaft near the stent mounting location enhances the device to delivering contrast medium efficiently and effectively. Fitz states that it is highly desirable to deliver contrast medium upstream of a diseased site in order to check the flow past the site, which enables the user to precisely position the device at the stenosis (Col 1, lines 5-20)

14. It would have been obvious to one of ordinary skill in the art at the time the invention was made to enhance the stent delivery system of Krivoruchko by adding a discharge opening for delivering contrast medium efficiently and effectively. Fitz provides the motivation that delivering contrast medium prior to stent delivery is a well-known improvement in the art of stent treatment. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

Response to Arguments

15. Applicant's arguments with respect to claims 10-29 anticipated by Krivoruchko have been considered but are moot in view of the new ground(s) of rejection.

16. Applicant's arguments filed 08/04/06 have been fully considered but they are not persuasive. Applicant has respectfully misinterpreted the rejection regarding the Mische reference. In the previous office action, examiner has not abandoned, but rather asserted, the analogy of the claimed inner member being analogous to inner catheter (72) of Mische and the claimed outer member being analogous to the outer catheter (70) of Mische.

17. Examiner acknowledges that applicant has addressed the double patenting rejection by stating a request to wait until indication of allowable subject matter. Respectfully, the rejection will remain in the action until it is further addressed.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh




ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

1/4/09